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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,899	05/31/2001	Mark E. Wilson	834460-68474	1013

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EXAMINER	
JIANG, SHAOJIA A	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 02/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/870,899	WILSON ET AL.	
	Examiner	Art Unit	
	Shaojia A Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2003 and 11 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8,9,13-20,23,25 and 71-102* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,9,13-20,23,25,41 and 71-102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed October 28, 2003 and December 11, 2003, wherein claims 10-12 are cancelled, and claims 1-6, 8-9, 13-20, 23, 25, and 41 have been amended, and claims 73-102 are newly submitted

It is noted that claims 7, 21-22, 24, 26-40, and 42-72 have been cancelled previously in Applicant's amendment filed May 9, 2003, recorded in the previous Office Action June 2, 2003.

Claims Claims 1-6, 8-9, 13-20, 23, 25, 41 and 71-72 as amended now, and new claims 73-102 are examined on the merits herein.

Applicant's amendment changing the limitation to a specific amount herein in claims 42 and 77 filed on December 11, 2003 with respect to the rejection of Claims 1-3, 5, 12-13, 15-17, 19-20, 23, 25, 41, and 71-72 made under 35 U.S.C. 102(b) as being anticipated by Fritsche et al. of record) for reasons of record stated in the Office Action dated June 2, 2003 have been considered and are found persuasive to remove this particular rejection. Therefore, the said rejection is withdrawn.

The declaration of Dr. Douglas M. Webel (inventor) submitted October 28, 2003 in under 37 CFR 1.132, is acknowledged and will be further discussed below.

The following is new rejections necessitated by Applicant's amendment filed on November 25, 2003.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 8-9, 13-20, 23, 25, 41 and 71-72 as amended now, and new claims 73-102, are rejected under 35 U.S.C. 103(a) as being unpatentable over Fritsche et al. (of record) in view of Boudreaus et al. (of record).

Fritsche et al. discloses that fish oil compositions (menhaden fish oil) which is known to comprise C20 and C22 omega-3 fatty acids including eicosapentaenoic acid and also comprise omega-6 fatty acids (see abstract, especially Table 1 at the left column of page 1842, and Table 2 at the right column of page 1843) are useful in dietary compositions to feed sows (female swine) including gestation until farrowing and lactation and methods of the treatment to benefit sow's performance in maternal period including gestation until farrowing and lactation, and benefit pig survival, number of pigs born per sow, birth weight and weaning weights (see title of the article, abstract, Introduction, and working examples in "Animals and Diets" at the right column of page 1841 to the left column of page 1842). Fritsche et al. also discloses the effective amounts of fish oil in the feed compositions to be administered daily, e.g., 3.5 or 7.0%,

and vitamin mix (known antioxidants) in the feed compositions (see abstract, especially Table 1 at the left column of page 1842).

Fritsche et al. does not expressly disclose the particular amounts (percentage) of fish oil in the composition there, 0.025% to 2% by weight, or the particular amounts fish oil such as salmon oil in the composition therein, and the ratio of omega-6 to omega-3 fatty acids, and the particular time for the administration such as about 30 days before a first mating through a second mating, and stabilizing the fish oil by prilling.

Boudreaux et al. discloses that the range of the ratio of omega-6 fatty acids to omega-3 fatty acids herein in the composition to be administered to animals is within the instant claim. See abstract and page 236 3rd paragraph of left column.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to optimize the amount of fish oils to 0.025% to 2% by weight in the prior art compositions and to optimize the particular ratio of omega-6 fatty acids to omega-3 fatty acids herein in the compositions herein.

One having ordinary skill in the art at the time the invention was made would have been motivated to optimize the amount of fish oils to 0.025% to 2% by weight in the prior art compositions since the effective amounts up to 3.5 or 7% of fish oil in the feed composition of Fritsche et al. are known in the art.

One having ordinary skill in the art at the time the invention was made would have been motivated to optimize the particular ratio of omega-6 fatty acids to omega-3 fatty acids herein in the compositions herein, since the range of the ratio of omega-6

fatty acids to omega-3 fatty acids herein in the composition to be administered to animals is known according to Boudreaux et al.

Moreover, the optimization of known effective amounts of known active agents to be administered based on the disclosures of the prior art is considered well in the competence level of an ordinary skilled artisan, involving merely routine skill in the art, especially considered well within **conventional** skills in animal science and animal feed industry.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Additionally, Omega-3 fatty acids in particular are known to be useful to increase female animal fertility (see Applicant's admission regarding the prior art at page 2 lines 29-30 of the specification). Omega-6 fatty acids are known to increase the number of live births in animals (see page 2 lines 24-25 of the specification). It is noted that Applicant clearly cited the prior art references, i.e., journal articles and patents, for these prior art teachings in the specification.

Further, Salmon oil or menhaden oil is well known to contain C20 and C22 omega-3 fatty acids and omega-6 fatty acids. C20 and C22 omega-3 fatty acids and omega-6 fatty acids are known to benefit female swine performance. Therefore, one of ordinary skill in the art would have found it obvious to employ Salmon oil or menhaden oil as fish oil and determine the particular amounts (percentage) of fish oil and the time

for the administration such as about 30 days before a first mating through a second mating based the prior art teachings.

Furthermore, one of ordinary skill in the art would have found it obvious to stabilize the fish oil in the feed by prilling since prilling is known as an art recognized technique for stabilizing fish oil.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims Claims 1-6, 8-9, 13-20, 23, 25, 41 and 71-72 as amended now, and new claims 73-102, are rejected under 35 U.S.C. 103(a) as being unpatentable Abayasekare et al. (of record).

Abayasekare et al. discloses that dietary fatty acid compositions, i.e., fish oil, comprising instant fatty acids such as omega-6 fatty acids to omega-3, and the their ratio of (see particularly Fig 1 at page 277) are useful in increasing the female performance, i.e., follicular development in the ovary, ovaulation, corpus luteum function, pregnancy, parturition, and lactation (see abstract, page 279-282).

Abayasekare et al. does not expressly disclose the dietary fatty acid compositions therein to be administered to female swine, and the particular amounts (percentage) of fish oil in the composition there, 0.025% to 2% by weight, or the particular amounts fish oil such as salmon oil in the composition therein, and the ratio of omega-6 to omega-3 fatty acids, and the particular time for the administration such as about 30 days before a first mating through a second mating, and stabilizing the fish oil by prilling.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to administer the dietary fatty acids to the particular female, swine in methods of increasing the reproductive performance of a female swine, increasing the number of live births to a female swine, increasing the total number of births to a female swine, increasing the farrowing rate of a female swine, or increasing the reproductive performance of a breeding population of a female swine. It would also have been obvious to a person of ordinary skill in the art at the time the invention was made to optimize the amount of fish oils to 0.025% to 2% by weight in the prior art compositions and to optimize the particular ratio of omega-6 fatty acids to omega-3 fatty acids herein in the compositions herein.

One having ordinary skill in the art at the time the invention was made would have been motivated to administer the dietary fatty acids to the particular female, swine in methods of increasing the reproductive performance of a female swine, increasing the number of live births to a female swine, increasing the total number of births to a female swine, increasing the farrowing rate of a female swine, or increasing the

reproductive performance of a breeding population of a female swine, since it is known that dietary fatty acid compositions, i.e., fish oil, comprising instant fatty acids are useful in increasing the female performance, i.e., follicular development in the ovary, ovaulation, corpus luteum function, pregnancy, parturition, and lactation, according to Abayasekare et al. One of ordinary skill in the art would acknowledge that female performance taught by Abayasekare et al. would encompass female swine. Therefore, one of ordinary skill in the art would have found it obvious to employ these fatty acids dietary composition to feed female swine for increasing the reproductive performance of a female swine, increasing the number of live births to a female swine, increasing the total number of births to a female swine, increasing the farrowing rate of a female swine, or increasing the reproductive performance of a breeding population of a female swine, with the reasonable expectation of success.

Additionally, Omega-3 fatty acids in particular are known to be useful to increase female animal fertility (see Applicant's admission regarding the prior art at page 2 lines 29-30 of the specification). Omega-6 fatty acids are known to increase the number of live births in animals (see page 2 lines 24-25 of the specification).

Moreover, as discussed above (see supra page 5-6) the optimization of known effective amounts of known active agents to be administered based on the disclosures of the prior art is considered well in the competence level of an ordinary skilled artisan, involving merely routine skill in the art, especially considered well within **conventional** skills in animal science and animal feed industry.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the teachings of the prior art.

Applicant's arguments filed on October 28, 2003 with respect to the rejection made under 35 U.S.C. 103(a) have been considered but are moot in view of the new rejections above.

Again, Applicant assertion in the declaration of Dr. Donal E. Orr (inventor) submitted February 10, 2003 under 37 CFR 1.132, with respect to that Applicants' claimed invention has met with great commercial success, have been fully considered but are not deemed persuasive. As discussed in the interview on October 15, 2003 regarding the instant case and the parent Application, the examiner directs Applicant's attention to MPEP 716.03(a) stating:

"Objective evidence of nonobviousness including commercial success must be commensurate in scope with the claims. In re Tiffin, 448 F.2d 791, 171 USPQ 294 (CCPA 1971) (evidence showing commercial success of thermoplastic foam "cups" used in vending machines was not commensurate in scope with claims directed to thermoplastic foam "containers" broadly). In order to be commensurate is scope with the claims, the commercial success must be due to claimed features, and not due to unclaimed features. Joy Technologies Inc. v. Manbeck, 751 F. Supp. 225, 229, 17 USPQ2d 1257, 1260 (D.D.C. 1990), aff 'd, 959 F.2d 226, 228, 22 USPQ2d 1153, 1156 (Fed. Cir. 1992) (Features responsible for commercial success were recited only in

allowed dependent claims, and therefore the evidence of commercial success was not commensurate in scope with the broad claims at issue.).

An affidavit or declaration attributing commercial success to a product or process "constructed according to the disclosure and claims of [the] patent application" or other equivalent language does not establish a nexus between the claimed invention and the commercial success because there is no evidence that the product or process which has been sold corresponds to the claimed invention, or that whatever commercial success may have occurred is attributable to the product or process defined by the claims. Ex parte Standish, 10 USPQ2d 1454, 1458 (Bd. Pat. App. & Inter. 1988)."

Secondly, Applicant's attention is directed to MPEP 716.03(b) stating:

"Gross sales figures do not show commercial success absent evidence as to market share, Cable Electric Products, Inc. v. Genmark, Inc., 770 F.2d 1015, 226 USPQ 881 (Fed. Cir. 1985), or as to the time period during which the product was sold, or as to what sales would normally be expected in the market, Ex parte Standish, 10 USPQ2d 1454 (Bd. Pat. App. & Inter. 1988)."

In the instant case, as discussed in the Final Rejection, the declaration merely shows the value of sales (US dollars) per the number pounds sold in the monthly sales for 2002 for Applicant's product Fertilium™, and the projected prediction of sale by 2004, absent a full market information and comparison, for example, with all other competitors and prices, and real sale information. Thus, the declaration of Dr. Donal E. Orr is insufficient to establish the fact that Applicants' claimed invention has met with great commercial success.

Therefore, as discussed above, the declarations of Dr. Stephen K. Webel, Dr. Douglas M. Webel (inventor), and Dr. Donald E. Orr (inventor) are ineffective to overcome the set forth 103(a) rejection.

The declaration of Dr. Douglas M. Webel (inventor) submitted October 28, 2003 in under 37 CFR 1.132, with respect to the composition of Fertilium™, has been fully considered. However, the exact and precise scope of the composition of Fertilium™, is not clearly disclosed, i.e., no factual documentary evidence is provided in support of the composition of Fertilium™. Hence, it is still unclear whether the evidence of commercial success asserted by Applicant is commensurate in scope with the claims, because the instant specification and the declaration fail to disclose what ingredients or agents in Applicant's product Fertilium™.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
February 13, 2004

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

2/22/04